

REMARKS

The Office Action of August 7, 2007, has been received and reviewed. Claims 1-10 and 13 are currently pending in the application. Claim 13 was previously withdrawn from consideration. Claims 1-10 are under consideration. Claims 1-10 stand rejected. Claim 1 stands objected to. Claim 1 is amended herein. New claims 14-19 are presented herein. All amendments are made without prejudice or disclaimer. No new matter has been presented. Reconsideration is respectfully requested.

Priority

Applicants note that the priority documents have not yet been provided to the Examiner. Applicants respectfully submit a certified copy of the priority document EP 01203760.

Claim Objection

Claim 1 stands objected to for containing a misspelling of the word “homologous.” Applicants submit that appropriate correction has been made.

Rejections under 35 U.S.C. § 112, Second Paragraph

“No significant homology with the silenced locus”

Claim 1 stands rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite. Specifically, it was asserted that the language “no significant homology with the silenced locus” was indefinite as it could not be determined whether the target gene as a whole does not have significant homology with the silenced locus or if it is just the region of at least 23 nucleotides. Office Action mailed August 7, 2007, at page 2. Applicants respectfully traverse the rejection as hereinafter set forth.

Although the applicants do not agree that any of the claims are indefinite, in order to expedite prosecution, claim 1 has been amended herein. Specifically, claim 1 has been amended to recite “wherein the target gene has no significant homology with the silenced locus.” Applicants respectfully submit that the above amendment addresses the Examiner’s concern regarding to which entity no specific homology is required.

In view of at least the foregoing, applicants respectfully request withdrawal of the rejection of claim 1 under 35 U.S.C. § 112, second paragraph, and reconsideration of same.

Distinct regions of the recombinant gene

Claim 1 stands rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite. Specifically, it was asserted that it was unclear if, on the recombinant gene, the region of at least 23 contiguous nucleotides that are at least 60% homologous with the silenced locus can overlap with, or whether its location is distinct from, the region that has at least 23 nucleotides that are at least 60% homologous with the target gene. Office Action mailed August 7, 2007, at pages 2-3. Applicants respectfully traverse the rejection as hereinafter set forth.

Although the applicants do not agree that any of the claims are indefinite, in order to expedite prosecution, claim 1 has been amended herein substantially as suggested by the Examiner. Specifically, claim 1 has been amended to recite “the recombinant gene comprises a first region of at least 23 contiguous nucleotides that are substantially identical with at least 23 contiguous nucleotides of the RNA-silenced locus and the target gene comprises a region of at least 23 contiguous nucleotides that are substantially identical with at least 23 contiguous nucleotides of a second region of the recombinant gene, but wherein the target gene has no significant homology with the RNA-silenced locus.” The term “substantially” is included as a modifier of the term “identical” to avoid the situation where one skilled in the art practices the present invention but, for example, makes an insubstantial change to a nucleotide, and thereby argues that the claim is not infringed. Having relinquished by amendment a scope which is supported by our present specification of 60% homology, in order to expedite prosecution, it is urged that the claim including the term “substantially” is definite on its face and one skilled in the art will appreciate what is meant and required to meet the limitation of substantial identity. Therefore, Applicants respectfully submit that the above amendment addresses the Examiner’s concern as it follows the language proposed by the Examiner.

In view of at least the foregoing, applicants respectfully request withdrawal of the rejection of claim 1 under 35 U.S.C. § 112, second paragraph, and reconsideration of same.

A host

Claims 3-6 stand rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite. Specifically, it was asserted that because the parent claim indicates “a” (one) host the child claims are indefinite because they require that the recombinant gene be introduced into multiple hosts. Applicants respectfully traverse the rejections as hereinafter set forth.

Applicants note that recitation of the indefinite article “a” in a patent claim does not denote “one” but carries the meaning of “one or more” in open ended claims using the transitional phrase “comprising.” *KCJ Corp. v. Kinetic Concepts Inc.*, 223 F.3d 1351, 55 USPQ2d 1835, 1839 (Fed. Cir. 2000). Unless the claim is specific as to the number of elements, the article “a” receives a singular interpretation only in rare circumstances when the patentee evinces a clear intent to so limit the article. *Id.* Under this conventional rule, the claim limitation “a,” without more, requires at least one. *Id.*

In view of the Federal Circuit’s decision in KCJ, applicants submit that “a host,” as used in claim 1, is properly understood as “one or more hosts.” Thus, applicants submit that claim 1 clearly supports claims 3-6 in indicating that the recombinant gene may be provided to multiple hosts.

In addition, applicants respectfully submit that there is nothing in claims 3-6 that requires that the recombinant gene be provided to multiple hosts. Applicants note that the elements of claims 3-6 could be met if the recombinant gene were provided to a single host on multiple occasions, thus “wherein the RNA silencing of the target gene is obtained more than 95% (85%) of the time in the host.

In view of at least the foregoing, applicants respectfully request the withdrawal of the rejections of claims 3-6 under 35 U.S.C. § 112, second paragraph, and reconsideration of same.

Rejections Under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 1-10 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly failing to comply with the enablement requirement. Specifically, it was asserted that

[T]he specification, while being enabling for the claimed method when the recombinant gene comprises of region of at least 23 nucleotides that are identical to the silenced locus, and when the target gene comprises a region of at least 23 nucleotides that are identical to the recombinant gene, does not reasonably provide enablement for the claimed method when the regions of homology are 32

nucleotides having less than 100% identity. Office Action mailed August 7, 2007, at page 4.

Applicants respectfully traverse the rejections as hereinafter set forth.

“The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.” *U.S. v. Teletronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988). Applicants respectfully submit that one of skill in the art could make and use the claimed invention without undue experimentation.

Although applicants do not agree that any of the claims lack enablement, in order to expedite prosecution, claim 1 has been amended herein. Specifically, claim 1, from which claims 2-10 depend, directly or indirectly, has been amended to recite “first region of at least 23 contiguous nucleotides that identical with at least 23 contiguous nucleotides of the RNA-silenced locus” and “region of at least 23 contiguous nucleotides that are identical with at least 23 contiguous nucleotides of a second region of the recombinant gene.” Thus, amended claim 1 should be considered enabled, *inter alia*, as “the specification, [is] enabling for the claimed method when the recombinant gene comprises of region of at least 23 nucleotides that are identical to the silenced locus, and when the target gene comprises a region of at least 23 nucleotides that are identical to the recombinant gene” as noted by the Examiner. Office Action mailed August 7, 2007, at page 4.

For at least the foregoing reasons, applicants respectfully submit that claims 1-10 are enabled. Consequently, applicants respectfully request withdrawal of the rejections of claims 1-10 under 35 U.S.C. § 112, first paragraph, for lack of enablement and reconsideration of same.

Rejections under 35 U.S.C. § 103(a)

Claims 1-10 stand rejected under 35 U.S.C. § 103(a) as assertedly being obvious over Van Houdt et al. (Mol. Gen. Genet., 2000, Vol. 264, pages 995-1002) (hereinafter “Van Houdt 1”) in combination with Depicker et al (Curr. Op. Cell Biol., 1997, Vol. 9, pages 373-382) (hereinafter “Depicker.”). Applicants respectfully traverse the rejections as herein after set forth.

Applicants note that to establish a *prima facie* case of obviousness the prior art or knowledge in the art **must teach or suggest all the claim elements**. *In re Royka*, 490 F.2d 981,

985 (CCPA 1974); *see also* MPEP § 2143.03. Applicants respectfully submit that the art relied upon by the Examiner and/or the asserted knowledge does not teach or suggest all the claim elements. Specifically, the art does not teach silencing a target gene “wherein the target gene has no significant homology with the silenced locus” as recited by amended claim 1.

Applicants note that where Van Houdt 1 silences a gene not previously silenced (a chimeric GUS gene), silencing occurs by virtue of containing a nptII region homologous to a silenced nptII locus. Thus, the recombinant GUS gene has significant homology with a silenced locus and therefore does not meet the above recited element of claim 1. As noted by the Examiner, Depicker teaches that gene silencing may occur *in trans* where the silenced locus has homology to the target sequence. Applicants respectfully submit that this teaching of Depicker, as relied on by the Examiner, does not teach a situation wherein the target gene to be silenced has no significant homology to the silenced locus; thus Depicker does not remedy the lack of teaching in Van Houdt 1. Further, applicants note that while Depicker teaches that gene silencing can be promulgated through 1 step *in trans*, neither Van Houdt 1 nor Depicker teach nor suggest that gene silencing can be promulgated through 2 steps *in trans* as is required to practice claim 1.

In addition, the Examiner asserts that if the GUS gene of Van Houdt 1 was replaced by a gene endogenous to the host plant, there would have been a reasonable expectation that the endogenous gene in the host plant would have been RNA-silenced as well. Office action mailed August 7, 2007, at page 8. Applicants respectfully submit that any reasonable expectation of success in this case can only be based on impermissible hindsight using the disclosure of the instant application. Applicants note that given the teachings of the Specification, there would be a reasonable expectation of success that the hypothetical endogenous gene in the host plant would have been RNA-silenced as well. However, absent the teachings of the Specification, applicants submit that there is no teaching in the cited art that RNA-silencing is able to proceed through 2 steps *in trans* and, given the unpredictable nature of the silencing arts, there would be no reasonable expectation of success in so doing.

The Examiner further asserts that a reasonable expectation of success is found given the knowledge of the PTGS pathway in the prior art at the time of filing. Applicants submit, as noted *supra*, that the knowledge in the prior art was limited to 1 step *in trans* gene silencing and

that there is no teaching, suggestion, or reasonable expectation of success provided by the prior art or the knowledge in the art that PTGS can proceed *in trans* through a 2 step process to yield silencing of a target gene “wherein the target gene has no significant homology with the silenced locus” as recited by amended claim 1.

Claims 1-10 stand further rejected under 35 U.S.C. § 103(a) as being unpatentable over Van Houdt *et al.* (Plant Physiol., 2003, Vol. 131, pages 245-253). As was noted by the Examiner, this reference is only available as prior art as the claim for priority in the instant application had not yet been perfected. Office Action mailed August 7, 2007, at page 8.

Applicants herewith perfect the priority claim by submitting, attached hereto, a certified copy of EP 01203760, filed May 10, 2001. Thus, Van Houdt *et al.* (Plant Physiol., 2003, Vol. 131, pages 245-253) should no longer be considered prior art for the instant application.

In view of at least the foregoing, applicants respectfully request the withdrawal of the rejections under 35 U.S.C. § 103(a) and reconsideration of same.

New Claim 16

With respect to “consisting essentially of”, applicants note that an exact and specific meaning has been provided by the courts. To wit: “consisting essentially of limits the scope of a claim to the specified materials or steps ‘and those that do not materially affect the basic and novel characteristic(s)’ of the claimed invention.” M.P.E.P. § 2111.03 citing *In re Herz*, 537 F.2d 549, 551-52 (CCPA 1976)(emphasis in original).

New Claim 18

Applicants note that new claim 18 is a means-plus-function claim and is thus entitled to examination under 35 U.S.C. § 112, ¶ 6. See M.P.E.P. § 2181.

CONCLUSION

In light of the above amendments and remarks, applicants respectfully request reconsideration of the application and a timely Notice of Allowance. If questions remain after

consideration of the foregoing, or if the Office should determine that there are additional issues which might be resolved by a telephone conference, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



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Date: February 7, 2008